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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,841	01/19/1999	RICHARD G. OLSEN	CIR20013	8242

266 7590 02/27/2004

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EXAMINER

SCHWADRON, RONALD B

ART UNIT PAPER NUMBER

1644

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/125,841

Applicant(s)

OLSEN ET AL.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-28 and 36-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 29-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

1. Claims 29-35 are under consideration. Claims 29-35 have been amended.

RESPONSE TO APPLICANTS ARGUMENTS

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration filed is defective because it has not been signed by inventor Olsen.

3. Regarding the claim to priority added in the amendment filed 6/12/2002, the phrase "based on" does not indicate the relationship of the instant application to PCT/US97/02309. The term "based on" should be removed and the phrase "is a 371 of" should be substituted.

4. Claims 29-35 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Claims 29-35 are indefinite in the recitation of "helper cells" because it is unclear what this means or encompasses. The term "helper cell" in itself has no art recognized meaning and is not defined in the specification. Therefore it is unclear what types of cells are encompassed by said term. A preferred substitution is "T helper cells".

Regarding applicants comments, whilst applicant has indicated that the instant rejection has been addressed by amending the claims to read "T helper cells", the instant claims have not been amended to read "T helper cells".

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 29-35 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Babbitt et al. (US Patent 5,766,920) for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Babbitt et al. teach expanded T helper cells from a patient which are expanded by treating mononuclear cells with antiCD3 antibody and IL-2 containing serum free conditioned media (see column 2 and column 3, second paragraph and column 9, first paragraph). There is no evidence of record that the particular culture conditions recited in the claims would have any particular effect on the treated cells. Babbitt et al. teach that this method can be used to produce cells from HIV patients (see column 7, third complete paragraph). While Babbitt et al. do not specifically teach that the cells used are obtained from lymph nodes of HIV patients, Babbitt et al. teach that lymph nodes are a known source of mononuclear cells (see column 2, third complete paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Babbitt et al. teach the claimed invention except for use of lymph node cells and Babbitt et al. teach that lymph nodes are a known source of mononuclear cells. One of ordinary skill in the art would have been motivated to create the claimed invention because Babbitt et al. teach expanded T helper cells from a patient (including HIV infected) which are expanded by treating mononuclear cells with antiCD3 antibody and IL-2 containing conditioned media and that lymph nodes are a known source of mononuclear cells.

Applicants arguments are based on an affidavit from a Dr. Triozzi that was supposed to be submitted with the instant amendment. However, no such declaration has been received. Therefore applicants comments related to said declaration have not been considered.

7. Claims 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ochoa et al. (US Patent 5,443,983) in view of prior art disclosed in the specification (page 4, lines 19-22).

Ochoa et al. teach that T cells from HIV patients can be cultured with antiCD3 antibody and IL-2 (see Abstract) resulting in the generation of T cells. While Ochoa et al. teaches that these cells are LAK cells, because the cells are from the same source and treated in the same manner as the cells of the claimed invention they would be expected to contain enriched T helper cells. Ochoa et al. teaches that the lymphocytes are preferably obtained from the individual (eg. HIV positive AIDS patient) to be treated. While Ochoa et al. do not specifically teach the use of lymph node cells, Ochoa et al. does teach that the cells used as a starting product can be derived from any tissue which is a source of lymphocytes (eg. lymph nodes). Furthermore, the specification discloses that art recognized that lymph node derived cells would have a superior locomotor ability and ability to traffic to lymph nodes in comparison to PBL (page 4, lines 19-22). Ochoa et al. teach that any art known media (eg. serum-free macrophage media) can be used to grow T cells as long as said media supports T cell growth (column 3, third paragraph). A routineer would have derived the particular dosage of IL-2 and antiCD3 antibody used in the instant invention by routine experimentation. Ochoa et al. teaches that said cells can be cultured with antiCD3 antibody and IL-2 for any desired period of time (see column 3, first paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Ochoa et al. teach that T cells from HIV patients can be cultured with antiCD3 antibody and IL-2 (see Abstract) and that the cells used as a starting product can be derived from any tissue which is a source of lymphocytes (eg. lymph nodes) while the prior art recognized that lymph node derived cells would have a superior locomotor ability and ability to traffic to lymph nodes in comparison to PBL .

Applicants arguments are based on an affidavit from a Dr. Triozzi that was supposed to be submitted with the instant amendment. However, no such declaration has been received. Therefore applicants comments related to said declaration have not been considered.

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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